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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/645,329 | 08/21/2003 | Amel Amblard | 8707-2160 | 7567 |

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| EXAMINER | |
|---|---|
| KRAMER, NICOLE R | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/04/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/645,329 | AMBLARD, AMEL | |
| | Examiner | Art Unit | |
| | Nicole R. Kramer | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12* is/are allowed.

6)☒ Claim(s) *13-15,17,19,20,23,24,26,28-35 and 39-41* is/are rejected.

7)☒ Claim(s) *16,18,21,22,25,27,36-38,42 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28, 29, 33, and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (U.S. Patent No. 6,389,316).

Regarding application of Bornzin et al. to the original subject matter of claims 28, 29, 33, and 35, please see the Non-Final Rejection mailed 3/7/2006 at page 6.

Further, with regards to the added amended subject matter "means for automatic mode commutation," Bornzin et al. discloses that the stimulation device is a dual chamber rate-responsive device with atrial tracking modes (such as DDD and DDDR) capable of switching to at least a non-tracking mode (such as DDI and DDIR) (see col. 4, lines 49-54). When an atrial capture assessment is needed, the device switches from an atrial tracking mode to an atrial non-tracking mode in order to prevent a PMT (see col. 4, lines 25-42 and col. 9, lines 35-40). Further, the device switches back from the atrial non-tracking mode to the atrial tracking mode when the atrial capture is present (see col. 5, lines 42-59).

Since the stimulation device of Bornzin et al. discloses verifies that atrial capture is present prior to switching back to an atrial tracking mode such as a DDD pacing

mode, Examiner considers the stimulation device to detect the claimed conditions "in order to prevent inappropriate switching to a DDD pacing mode."

Further, Examiner notes that the recitation "in order to prevent inappropriate switching to a DDD pacing mode" is an intended use recitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the stimulation device of Bornzin et al. includes means for mode switching, it is considered capable of utilizing the detected conditions in order to prevent inappropriate switching to a DDD pacing mode.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 30-32 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. (U.S. Patent No. 6,389,316), as applied to claims 29 and 35 above, in view of Markowitz et al. (U.S. Patent No. 5,601,615).

Regarding application of Bornzin et al. and Markowitz et al. to the original subject matter of claims 30-32 and 39-41, please see the Non-Final Rejection mailed 3/7/2006 at pages 6-7.

5. Claims 13-15, 17, 23, 24, 26, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (U.S. Patent No. 5,476,486) in view of Bornzin et al. (U.S. Patent No. 6,389,316).

Regarding application of Lu et al. to the original subject matter of claims 13-15, 17, 23, 24, 26, 33-35, please see the Non-Final Rejection mailed 3/7/2006 at pages 3-4.

Lu relates to determining the minimum pacing energy to capture the atrial chambers of the heart (see col. 1, lines 10-15), or in other words, determining the atrial capture threshold. With regards to the added amended subject matter "means for automatic mode commutation," Lu fails to disclose that the pacemaker may include means for mode switching. Bornzin et al. also relates to determining/adjusting the atrial capture threshold. When an atrial capture assessment is needed, the stimulation device of Bornzin et al. switches from an atrial tracking mode to an atrial non-tracking mode in order to prevent a PMT (see col. 4, lines 25-42 and col. 9, lines 35-40). Further, the device switches back from the atrial non-tracking mode to the atrial tracking mode once it is determined that atrial capture is present (see col. 5, lines 42-59). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the device of Lu et al. to include the automatic mode switching capabilities as taught in Bornzin et al. in order to prevent a PMT during the atrial capture assessment.

Since the stimulation device of Bornzin et al. discloses verifies that atrial capture is present prior to switching back to an atrial tracking mode such as a DDD pacing

mode, Examiner considers the stimulation device to detect the claimed conditions "in order to prevent inappropriate switching to a DDD pacing mode."

Further, Examiner notes that the recitation "in order to prevent inappropriate switching to a DDD pacing mode" is an intended use recitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the stimulation device of Bornzin et al. includes means for mode switching, it is considered capable of utilizing the detected conditions in order to prevent inappropriate switching to a DDD pacing mode.

6. Claims 13-15, 19, 20, 28-30, 33-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markowitz et al. (U.S. Patent No. 5,601,615) in view of Bornzin et al. (U.S. Patent No. 6,389,316).

Regarding application of Lu et al. to the original subject matter of claims 13-15, 19, 20, 28-30, 33-35, and 39, please see the Non-Final Rejection mailed 3/7/2006 at pages 4-5.

Markowitz et al. relates to determining/adjusting stimulation energy for capture of the heart in both chambers of the heart (see col. 1, lines 10-15), or in other words, determining the atrial capture threshold. With regards to the added amended subject matter "means for automatic mode commutation," Markowitz et al. fails to disclose that the pacemaker may include means for mode switching. Bornzin et al. also relates to

determining/adjusting the atrial capture threshold. When an atrial capture assessment is needed, the stimulation device of Bornzin et al. switches from an atrial tracking mode to an atrial non-tracking mode in order to prevent a PMT (see col. 4, lines 25-42 and col. 9, lines 35-40). Further, the device switches back from the atrial non-tracking mode to the atrial tracking mode once it is determined that atrial capture is present (see col. 5, lines 42-59). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the device of Markowitz et al. to include the automatic mode switching capabilities as taught in Bornzin et al. in order to prevent a PMT during the atrial capture assessment.

Since the stimulation device of Bornzin et al. discloses verifies that atrial capture is present prior to switching back to an atrial tracking mode such as a DDD pacing mode, Examiner considers the stimulation device to detect the claimed conditions "in order to prevent inappropriate switching to a DDD pacing mode."

Further, Examiner notes that the recitation "in order to prevent inappropriate switching to a DDD pacing mode" is an intended use recitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the stimulation device of Bornzin et al. includes means for mode switching, it is considered capable of utilizing the detected conditions in order to prevent inappropriate switching to a DDD pacing mode.

***Allowable Subject Matter***

7. Claims 1-12 are allowed.

8. Claims 16, 18, 21, 22, 25, 27, 36-38, 42, and 43 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

9. Please see the Non-Final Rejection mailed 3/7/2006 at pages 7-10 for the statement of reasons for the indication of allowable subject matter.

***Response to Arguments***

10. With respect to applicant's arguments of claims rejected as anticipated by Lu et al. and Markowitz et al., the arguments have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments with respect to the Bornzin et al. reference filed 9/7/06 have been fully considered but they are not persuasive. More specifically, Applicant argues that Bornzin et al. is directed towards adjusting the atrial capture threshold, and does not disclose detecting the claimed conditions in order to prevent inappropriate switching to a DDD pacing mode (see pages 16-17 of Response filed 9/7/2006).

However, as described above, with regards to the added amended subject matter "means for automatic mode commutation," Bornzin et al. discloses that the stimulation device is a dual chamber rate-responsive device with atrial tracking modes (such as DDD and DDDR) capable of switching to at least a non-tracking mode (such as DDI and DDIR) (see col. 4, lines 49-54). When an atrial capture assessment is needed, the device switches from an atrial tracking mode to an atrial non-tracking mode

in order to prevent a PMT (see col. 4, lines 25-42 and col. 9, lines 35-40). Further, the device switches back from the atrial non-tracking mode to the atrial tracking mode when the atrial capture is present (see col. 5, lines 42-59).

With regards to the amended subject matter that the claimed conditions are detected "in order to prevent inappropriate switching to a DDD pacing mode," since the stimulation device of Bornzin et al. discloses verifies that atrial capture is present prior to switching back to an atrial tracking mode such as a DDD pacing mode, Examiner considers the stimulation device to detect the claimed conditions "in order to prevent inappropriate switching to a DDD pacing mode."

Further, Examiner notes that the recitation "in order to prevent inappropriate switching to a DDD pacing mode" is an intended use recitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the stimulation device of Bornzin et al. includes means for mode switching, it is considered capable of utilizing the detected conditions in order to prevent inappropriate switching to a DDD pacing mode.

## *Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Tuesdays and Fridays, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRK
3/20/2007

George Manuel
Primary Examiner